GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1896
ANSWERED ON:08.03.2013
QUALITY OF GENERIC DRUGS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has put in place any mechanism to ensure the quality of generic and non-branded drugs in the country;

(b) if so, the details thereof along with the steps taken/proposed to strengthen them;

(c) whether the Government is considering to ban manufacturing ana marketing of generic drugs under the brand names of pharmaceutical companies;

(d) if so, the details thereof and the reasons therefor; and

(e) th`e steps taken/proposed by the Government to standardise various drug regulations relating to research, storing of raw materials and manufacturing of drugs, particularly generic drugs in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b): Yes. The quality of drugs, whether generic or non-branded or branded manufactured or imported for sale in the country is regulated under the provisions of the Drugs and Cosmetic Act, 1940 and the Drugs and Cosmetic Rules, 1945 made thereunder. Under these laws, the manufacture and sale of drugs are regulated by the State Governments and the import, approval of new drugs and banning of drugs are regulated by the Central Government through its drug regulatory body, namely, the Central Drugs Standard Control Organisation (CDSCO).

In order to strengthen these institutions, the Government has created 216 additional posts in CDSCO since 2008. The Central Drugs Testing Laboratories have been provided new sophisticated testing equipments. Two Sub-zones of CDSCO (Hyderabad and Ahmadabad) have been upgraded to full zones and three neifjsub-zones (Bangalore, Chandigarh and Jammu) have been created. The schwe of regular overseas inspection of manufacturing facilities situated abroad has been initiated to ensure proper compliance of good manufacturing practices guidelines before registering them for import of drugs. Two such inspections have already taken place in China. The National Pharmacovigilance Programme has been launched to capture Adverse Drugs Reaction {ADRs) for safe-guarding public health. 60 ADR Monitoring Centres are already functioning besides the National Coordination Centre at the Indian Pharmacopoeia Commission, Ghaziabad (U.P.) and a Pharmacovigilance Cell at CDSCO (Headquarters).

The State Governments have also been requested to strengthen their manpower and infrastructure. On its part, the Central Government has been extending financial assistance to them for upgradation of their infrastructure under the National Rural Health Mission. Further, during the 12th Five Year Plan, it has initiated a new scheme for providing financial assistance to the States / UTs for strengthening of State Drug Control Departments.

(c) & (d): At the time of the grant of the license for manufacture of a drug formulation, the trade name as submitted by the manufacturer was also being endorsed by the State Licensing Authorities alongwith proper name of the product thereby giving legitimacy to market the drug under the brand or the trade name. This practice was not in accordance with the spirit of the law, which does not require mentioning of any Trade Name / Brand Name on the applications or various forms for grant / renewal of a license to manufacture for sale or distribution. To check this practice, the Central Government issued a statutory direction to the State / UT Governments on 1.10.2012 under Section 33P of the Drugs & Cosmetics Act, 1940 to instruct their respective drug licensing authorities to grant / renew licenses to manufacture for sale or for distribution of drugs in proper / generic names only.

(e): The regulatory` provisions for manufacture, import and sale of drugs, including generic drugs, are enshrined in the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 made thereunder.